

**MEDICAL LABORATORY BOARD  
MINUTES**

**Date:** April 13, 2006

**Time:** 9:00 a.m., CDT

**Location:** Cumberland Room  
Ground Floor, Cordell Hull Building  
425 Fifth Avenue North  
Nashville, TN 37247

**Members Present:** Linda Lahr, MT Chairman  
Jere Ferguson, MD, Vice-Chairman  
Edward McDonald, MD  
John C. Neff, MD  
Trudy Papuchis, MD  
Thomasa Cooper, Medical Technologist  
Norman Crowe, Independent Laboratory Manager/Representative  
Yvonne Davis, Medical Technologist  
Martha Duncan, Medical Technologist  
Gloria Jenkins, Citizen Representative  
Alison McDonald-Spakes, Cytotechnologist  
Delores Voigt, MT Hospital Administrator

**Members Absent:** Dennis Carter, MD

**Staff Present:** Lynda S. England, Medical Technologist, Director  
Cheryl H. Thacker, Medical Technologist, Consultant  
Jerry Kosten, Rules Manager  
Robert Kraemer, Jr., Advisory Attorney  
Julia Daniels, Medical Technologist Consultant/ Surveyor  
East Tennessee Regional Office  
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,  
Middle Tennessee Regional Office  
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,  
Middle Tennessee Regional Office  
Mary Hamblen, Medical Technologist Consultant/Surveyor  
West Tennessee Regional Office  
Karon Daniels, Medical Technologist Consultant/ Surveyor,  
West Tennessee Regional Office

**Staff Absent:** Robbie Bell, Director-Health Related Boards, Ex-Officio Board Member

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**CLIA Representative:** Irmgard Brown, CLIA Manager

**Quorum:** A sufficient number of board members were present to constitute a quorum.

**Presiding Officer:** The meeting was called to order by the Board Chairman, Linda Lahr at 9:01 a.m.

Ms. Lahr introduced the (2) newly appointed members to the Board: Ms. Gloria Jenkins, citizen representative, and Trudy Papuchis, MD representing the hospital/laboratory manager-administrative directors in Tennessee.

Ms. Delores Voigt was reappointed to serve another term representing hospital administrators in Tennessee.

The Board members introduced themselves to the audience.

**Welcome:** Ms. Lahr welcomed the guests and visitors to the board meeting.

**Board Minutes:** A motion to approve the January 11, 2006 Personnel & Education Committee minutes was made by Dr. McDonald.  
Second: Dr. Neff  
These minutes were approved.

A motion to approve the Board minutes from the January 12, 2006 meeting was made by Dr. McDonald.  
Second: Dr. Neff.  
The minutes were approved.

**Board Report**  
**Personnel & Education Committee:**

Ms. Duncan presented a report of the actions of the Personnel & Education Committee meeting held on April 12, 2006.

Motion to accept this report: Dr. Ferguson.  
Second: Dr. McDonald.  
The report was approved.

**Contested Cases:** There were no contested cases presented during this meeting.

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**Board Report-Tennessee Professional Peer Assistance Program:**

Mike Harkreader, MA, RN  
TNPAP State Director

Mr. Harkreader gave the following report to the board:

Statistics for the period July 1, 2005 to March 31, 2006 stated there were thirteen (13) referrals with four (4) individuals in monitoring status and one (1) individual in the evaluation status.

One (1) individual refused to participate in the program and was reported to TDOH and four (4) individuals were found to not need monitoring.

There were a total of seven (7) individuals discharged from this program with one (1) successful completion of the program.

The reason for the referrals to TNPAP indicated a history of arrest and a history of substance abuse. All thirteen (13) referrals were from the Board's administrative office.

TNPAP can take referrals on individuals with mental health issues and boundary violations (sexual boundaries, anger management, etc.) Individuals with major depression, PTSD or anxiety disorders may also be referred to TNPAP per Mr. Harkreader.

Motion to accept this report: Dr. McDonald.  
Second: Dr. Neff.  
Approved.

A copy of Mr. Harkreader's report is on file in the board's administrative office.

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Board members voted to continue the TNPAP contract with no changes.  
This contract is renewed for the 2006-2007 fiscal year.

Motion: Dr. Neff.  
Second: Ms. Duncan.  
Approved.

**Board Report-Rules:**  
Jerry Kosten-Rules Manager

*A. Rules Amendments:*

Mr. Kosten reported on a rulemaking hearing held March 17, 2006  
concerning the following amendments to:

1-Rule 1200-6-1-.01 Licensure of Special Analysts  
Chemical Terrorism-State Laboratory Services

This rule was amended to state...Chemical Terrorism Level II  
*Laboratories*...on a motion filed by Dr. McDonald.  
Second: Dr. Neff.  
Amendment approved.

2-Rule 1200-6-1.21 Qualifications & Duties of Medical  
Laboratory Supervisor.

3-Rule 1200-6-1-.22-Qualifications, Responsibilities &  
Duties of Testing Personnel.

4-Rule 1200-6-3-.03 Change in Location, Director, Owner,  
Supervisor or Testing Menu in a Medical Laboratory.

5-Rule 1200-6-3-.02 Licensing Fee-Facilities.

6-Rule 1200-6-3-.16 Physician Office Laboratories (POL's).

There were no comments during the rulemaking hearing .

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A motion to adopt these amendments was made by Dr. McDonald.  
Second: Dr. Neff.

A roll call vote was taken with all members present voting aye.

**B. Authorize Rulemaking Hearing:**

The board authorized a rulemaking hearing to be held June 16, 2006 concerning amendments to:

1-Rule 1200-6-1-.06 Fees.

2- Rule 1200-6-1-.12 Continuing Education Requirements.

3-Rule 1200-6-3-.02 Licensing Procedures.

4-Rule 1200-6-3-.21 Renewal of Laboratory License.

5-Rule 1200-6-3-.22(1) (a) 5-Pathway for MT License.

A motion to authorize a rulemaking hearing was made by. Dr. McDonald.  
Second: Dr. Neff.  
Approved.

**Ratifications:**

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

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**Board Director's Report/Discussion:**

Lynda S. England BS MT(ASCP)  
Director

Ms. England reported quarterly administrative office/staff activities to the Board members. This report included administrative office statistics, referrals from this office for TNPAP for peer assistance services and website update information.

Motion: Ms. Voigt.  
Second: Ms. Duncan.  
Report Approved.

The complete director's report is filed in the administrative office.

**Direct More Than Three (3) Labs  
Rule 1200-6-3-.13(5) Medical Lab Facilities:**

There were no requests made to the Board during this meeting.

**Reinstatement of License:** There were no requests for licenses to be reinstated during this meeting.

**Reports/Discussion:**

**Reports:**

Regional Consultant/Surveyor – Proficiency Testing (PT) &  
Complaint Investigations/Licensed Laboratory Facilities

**East Tennessee Regional Office**

Julia Daniels, Consultant II/Surveyor;

*Unsatisfactory/ Unsuccessful Proficiency Testing:*

The East Tennessee Regional Office reported zero (0) facilities with a first occurrence of unsuccessful participation in proficiency testing events.

*Complaint Investigations:* The East Tennessee Regional Office conducted zero (0) investigation(s) during the last quarter of 2006.

**Middle Tennessee Regional Office**

Sandra S. Bogard, Consultant II/Surveyor  
Onezean Otey, Jr., Consultant I/Surveyor

Mr. Otey gave the report:

*Unacceptable/Unsuccessful Proficiency Testing:*

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) was zero (0).

*Complaint Investigations:*

The Middle Tennessee Regional Office has conducted zero (0) complaint investigation(s) during this quarter.

**West Tennessee Regional Office**

Mary J. Hamblen, Consultant II/Surveyor  
Karen Daniels, Consultant I/Surveyor

Ms. Daniels gave the report:

*Unacceptable/Unsuccessful Proficiency Testing:*

The number of state licensed laboratories with first occurrence of unsuccessful proficiency testing (two out of three in a row) is two (2).

Each facility provided the surveyor with an acceptable Plan of Correction.

*Complaint Investigations:*

There were zero (0) complaint investigations from the West Tennessee Regional Office this quarter.

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Motion to accept these regional reports: Dr. Ferguson.  
Second: Dr. Ferguson.  
Report Approved.

**Discussion/Clarification for Staff and Surveyors:**

Request for clarification:

1-Amy Webster, MT (ASCP), CLCP  
American Esoteric Laboratories  
Memphis, TN 38141

1-The Board was asked to clarify individuals who could perform the following technical preparatory procedures per Rule 1 200-6-3-.19  
Preparatory Portions of Specimens, relating to cytology:

a-preparation of liquid-based smears using Cytoc or SurePath instrumentation.

b-staining of pap smears and non-GYN cytological smears.

c-loading of slides into racks for cytological imaging.

After discussion, the Board agreed the analytical phase begins with the evaluation of screening a prepared cytological specimen. Any activity required prior to microscopic review of cytology specimens will become item (g) of Rule 1200-6-3-.19.

2-Jim Wells, BS, RRT  
Director of Pulmonary Services  
Memorial Health Care System  
Chattanooga, TN 37404

Mr. Wells requested the Board clarify the use of an instrument primarily used to determine the pH of blood gases be utilized in the determination of the pH of body fluid, specifically pleural fluid. These specimens are collected in the same manner as blood gases. There is a CAP proficiency test available for use. Mr. Wells was unsure if this additional analysis would be acceptable laboratory practice in an arterial blood gas laboratory licensed separately from the main clinical lab.



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There is no conflict with the practice of respiratory care per the Board of Respiratory Care's scope of practice for its licensees.

The Board determined that this practice was acceptable on a motion presented by Dr. Neff.

Second: Dr. McDonald.

Approved.

The Board requested that all facility licenses be modified to state "pH/Blood Gases" instead of the current "Arterial Blood Gases and pH".

Motion: Dr. McDonald

Second: Dr. Neff.

Approved.

The Board also requested a review of all Rules pertaining to Medical Laboratories to determine any rule needs to be amended to reflect the terminology "pH/Blood Gases". Staff will perform that task.

A motion to amend any rule to reflect this "nomenclature" was made by Dr. McDonald.

Second: Dr. Ferguson

Approved.

3-Timothy A. Robert, Ph.D., DABCC

Beverly Cauthon

Aegis Analytical Laboratories

Nashville, TN 37210

Representatives from this licensed facility appeared before the Board to request a ruling regarding the toxicological testing of patient samples for the purposes of compliance assessment/pain management. The request was for the Board to consider the testing procedures on those individuals to be classified as non clinical but forensic testing procedures. This classification would allow non laboratory licensed personnel to perform and report these test results.

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After discussion the Board determined the Rules for Medical Laboratories do not distinguish clinical laboratories from forensic laboratories. Board members agreed laboratory testing procedures performed on patients for pain management purposes must be in a state licensed lab facility because these tests are diagnostic. Medical laboratory professionals licensed in Tennessee must perform these analyses.

**Department Reports/Discussion:**

**Health Related Board's Report/Discussion:**

Robbie Bell, Director

Ms. Bell did not give a report during the board meeting.

**Office of General Counsel Report:**

Robert J. Kraemer, Jr.  
Advisory Attorney

Mr. Kraemer led the discussion of the following items:

**Criminal Background Checks & Screenings (05-1026)**-The rulemaking hearing was held on March 24, 2005 and these amendments were adopted by the Board on April 14, 2005. They were sent to the Attorney General on April 19, 2005. They were filed with the Secretary of State on March 14, 2006 and become effective on May 28, 2006.

**Director, Delegation, Reportable Cultures and POC (05-1170)**-The rulemaking hearing was held on July 8, 2005 and these amendments were adopted by the Board on July 14, 2005. They were sent to the Attorney General on July 21, 2005. They were filed with the Secretary of State on February 15, 2006 and become effective on May 1, 2006.

**2005 Legislation Amendments (05-1327)**-The rulemaking hearing was held on September 26, 2005, with the amendments adopted by the Board on October 13, 2005. They were sent to the Attorney General on October 18, 2005 and are still there.

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**Alternative Site Testing and Reportable Cultures (05-1549)**-The rulemaking hearing was held on December 16, 2005 and these amendments were adopted by the Board on January 18, 2006. They were sent to the Attorney General on January 18, 2006 and they are still there.

**POL, Bio-Terrorism and Licensure Change Amendments-(06-1010)**-The rulemaking hearing was held on March 17, 2006 and after response to comments, these amendments are ready for adoption at this meeting.

**Litigation:**

The Office of General Counsel currently has zero (0) open disciplinary cases pertaining to the Medical Laboratory Board.

**Topics for Discussion:** None.

Motion to Accept Report: Dr. Ferguson.  
Second: Dr. Neff.  
Report Approved.

**Bureau of Investigations (BIV) Report:**

Mr. Kraemer gave this report from information provided by the Bureau of Investigation which included four (4) old complaints from 2005 in that department.

Currently per Mr. Kraemer's report there are zero (0) new complaints in BIV for review.

Motion to Accept Report: Ms. Duncan.  
Second: Ms. Voigt.  
Report Approved.

**Office of Health Licensure & Regulation:**

Judy Eads, RN  
Assistant Commissioner of Health

No report was given by Ms. Eads during this meeting.

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**Financial Report:**

Lisa Tittle  
Fiscal Officer

A copy of the financial report for the fiscal year 2005-2006 was mailed to each board member earlier in the month. A copy of this report is included in each member's board book and also on file in the administrative office.

**Waived Testing Procedures:**

Edward R. Davis, MD  
Associate Medical Director  
Methodist Healthcare System  
Memphis, TN  
Nancy E. Cahill, J.D.  
Biosite Triage® BNP Test System

Dr. Davis and Ms. Cahill appeared before the Board to request that the Biosite Triage® BNP Test System for Cardiac Markers and BNP analyses be placed on the point of care waived test list.

After discussion Board members requested documentation be provided to the Board as to:

- 1-documentation as to the quality of patient care and patient outcome be improved by moving this test from an exempt test to a waived test status for the citizens of Tennessee and
- 2-documentation of a comparison study found in peer review literature concerning the comparison of precision and accuracy in testing values obtained from "mall walkers" who perform this test and medical laboratory professionals who perform the test.

A motion to deny this request was made by Dr. Neff.  
Second: Dr. McDonald.  
Request was denied.

Ms. Davis recused herself from the discussion and vote.

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**Review Eligibility of Medical Laboratory Director:**

There were no candidates for board approval presented during this meeting.

**Board Policy:**

The Board voted to adopt a revised policy for staff utilization in the processing of applications for the licensure, renewal and reinstatements of medical laboratory professionals. Guidelines were established to determine the necessity of an applicant's appearance before the Personnel & Education Committee and/or referral to the TnPAP (the Board's Professional Assistance Advocacy Program) relative to criminal convictions noted on an application submitted to the Board's Administrative Office.

*Note: This revised policy may be viewed on the Board's webpage ([www.state.tn.us/gov](http://www.state.tn.us/gov)) (go to the search engine and type medical laboratory board) under the heading Policy Statements.*

Motion for adoption: Dr. Neff  
Second: Ms. Duncan  
Approved.

**Other Business:**

No other business discussions during this meeting.

**Statement of Next Meeting:**

The next meeting will be held July 13, 2006 beginning at 9 am, CDT at the Millennium Maxwell House 2025 Metrocenter Blvd. Nashville, TN 3728.

**Record of Adjournment:**

The meeting adjourned at 1:37 pm CDT on a motion properly filed by: Ms Duncan.  
Second: Dr. Papuchis.  
Approved.

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Linda Lahr, MT  
Chairman, Tennessee Medical Laboratory Board

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Date

## **REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES**

1. **Methodist Healthcare North Hospital**  
**3960 New Covington Pike**  
**Memphis, TN 38128-2504**

Facility Representative: Jane Nichols, MT (ASCP)  
Manager & POC Coordinator Laboratory Services

This facility request was to:

1-Permit Registered Nurses (RN's), EMT IV's and Paramedics to perform and report BNP Testing procedures utilizing the Biosite Triage Meter in the Emergency Department (ER) and

2-Permit EMT IV's and Paramedics to perform and report Cardiac Panels (CK-MB, Myoglobin, Troponin T) on the Biosite Triage Panel in the Emergency Department. (Extension of licensed personnel per earlier exemption granted 07/05/04).

Approval granted for both requests upon approval of scope of practice from Emergency Medical Services Board for their licensees, (EMT IV's). The training and oversight is the same as for nurses.

The EMT IV's are employees of Methodist Hospital and work in the Emergency Room.

Motion: Dr. Neff  
Second: Dr. Ferguson  
Approved.

Ms. Davis recused herself from the discussion and vote.

2. **Middle Tennessee Medical Center**  
**400 North Highland Avenue**  
**Murfreesboro, TN 37133-1178**

Facility Representative: Marvin Wagster  
Administrative Director of Laboratories  
Mary Lou Turpin, MT  
Point of Care Testing/Outreach Services

This facility request was for:

- 1-Registered Nurses (RN's) to perform and report blood gases, ionized calcium, electrolytes, BUN, creatinine, glucose, hematocrit, and PT/INR utilizing the i-STAT system hospital-wide and
- 2-Respiratory Therapists to perform blood gases throughout the hospital utilizing the i-STAT system.

Motion: Dr. Neff.  
Second: Dr. Ferguson.  
Approved.

Dr. McDonald and Ms. McDonald-Spakes recused themselves from the discussion and vote.

3. **Methodist University Hospital**  
**1265 Union Avenue**  
**Memphis, TN 38104**

Facility Representative: Jane Nichols  
Manager & POC Coordinator Laboratory Services

This request was for Registered Nurses to perform and report urine dipstick analyses in the Cancer Care Center utilizing the Bayer Clinitek STATUS analyzer.

Motion: Dr. McDonald.  
Second: Dr. Neff.  
Approved.

Ms. Cooper recused herself from the discussion and vote.

4. **StoneCrest Medical Center**  
**200 StoneCrest Blvd.**  
**Nashville, TN 37167**

Facility Representative: Sarah Beecham  
Director of Laboratory Services

This facility requested the Board approve the following exemptions:

1-Registered Nurses (RN's), to perform and report activated clotting times (ACT's) in the Cardiovascular Laboratory (CVL) utilizing the Hemochron, Jr. Signature Elite instrument and

2-Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) to perform and report CK-MB, Myoglobin, Troponin-I and BNP in the Emergency Department (ER) utilizing the Biosite Triage® Instrument and

Motion: Dr. McDonald.  
Second: Dr. Neff.  
Approved. (Both exemptions 1-2)

3-Phlebotomists to perform and report Ivey Bleeding Times throughout this facility.

Motion: Dr. Neff  
Second: Dr. McDonald  
Approved.

Ms. Duncan recused herself from the discussion and vote.

5. **LeBonheur Children's Medical Center**  
**50 North Dunlap**  
**Memphis, TN 38103**

Facility Representative: Cathy Connelly  
Administrative Director Operations

This facility request was to permit Certified Registered Nurse Anesthetists, Perfusionists, Registered Nurses (RN's), Registered Respiratory Therapists, Certified Respiratory Therapists and Registered Radiological Technologists to perform and report blood gases, sodium, potassium, ionized calcium, glucose, hematocrit, BUN, chloride, lactate and creatinine throughout this facility utilizing the i-STAT instrument and methodologies. (Extension of previously granted request)



Motion: Dr. Neff  
Second: Dr. McDonald  
Approved.

Ms. Davis recused herself from the discussion and vote.

6. **Centennial Medical Center**  
**2300 Patterson Street**  
**Nashville, TN 37203**

Facility Representative: Mollie Wynn, MT (AMT)  
POC Coordinator

This facility request was for:

1-Nurse Practitioners and Nurse Midwives to perform and report AmniSure® Rupture of Membranes Test in the Women's OB Triage Unit.

This is a test in kit form which is specific for the protein in amniotic fluid. There is no other facility in Nashville performing this test and the validation studies have not been completed. A motion for provisional approval with a completed validation report presented to the Board, October 12, 2006 was made by Dr. McDonald.  
Second: Dr. Neff.  
Provisional Approval.

2-Licensed Respiratory Therapists to perform and report blood gases, electrolytes, glucose, ionized calcium, hemoglobin and hematocrit in the Intensive Care Units utilizing the i-STAT instrument and methodologies.

Motion: Dr. Neff.  
Second: Dr. Ferguson  
Approved.

Ms. Duncan recused herself from these discussions and vote.

7. **Diagnostic Laboratories-VUMC**  
**22<sup>nd</sup> & Pierce 4605 TVC**  
**Nashville, TN 37232-5310**

**Facility Representative: Tom Aldridge**

This request was for Registered Nurses (RN's) to perform and report serum pregnancy testing procedures in the Medical Center North Clinical Research Center (GCRC) utilizing the Genzyme OSOM hCG Combo Test.

Motion: Dr. McDonald.  
Second: Dr. Neff.  
Approved.

8. **Baroness Erlanger Medical Center**  
**975 East Third Street**  
**Chattanooga, TN 37403-2112**

Facility Representative: Mary Hooper, MT  
Point of Care

This request was for Licensed Perfusionists to perform and report activated clotting times (ACT's), Heparin Dose Response, and Heparin Assay analyses in the Cardiovascular Operating Room utilizing the HMS Plus Hemostasis Management System.

Motion: Dr. Neff.  
Second: Dr. McDonald.  
Approved.

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Attachment 2  
Initial Facility Licenses  
Medical Laboratory Board  
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**INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION:**

1-Lab Corp of America PSC Kingsport  
1936 Brookside Drive Suite C  
Kingsport, TN 37660

Medical Laboratory Director: Susan Rollins, M.D.  
Anatomic/Clinical Pathology

Specialties: Collection Station

Surveyor: Julia Daniels, Consultant II/Surveyor  
East TN Regional Office

Motion: Dr. McDonald.  
Second: Dr. Ferguson.  
Approved.